CLAIMS

1-103. Cancelled.

104. (New) An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising:

a strip body including an edge extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge, the capillary channel extending from the sample application port to at least the vent;

at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the perimetric edge;

a test reagent adjacent at least the working electrode; and

visualization means associated with the capillary channel for enabling a user to visually identify when a sufficient amount of blood sample has been added to the capillary fill chamber to accurately perform a test, said visualization means including a solid, transparent or translucent viewing material extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel including at said working electrode and at least a portion of said counter electrode.

105. (New) The test strip of claim 104 in which said visualization means includes a means for identifying when a minimum sample amount has been added to the capillary channel.

106. (New) The test strip of claim 104 in which said visualization means includes said strip body including a color in the area adjacent the capillary channel which contrasts with the color of the sample as viewed through the viewing material, whereby the user is able

to visually locate the sample within the capillary channel by observation through the viewing material.

107. (New) The test strip of claim 104 in which said strip body includes opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge, to at least one of the electrodes.

108. (New) The test strip of claim 107 in which said strip body further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes.

109. (New) The test strip of claim 108 in which the opaque portions are spaced apart to reveal greater than about 75% of the width of the capillary channel.

110. (New) The test strip of claim 109 in which the opaque portions are aligned with the opposed sides of the capillary channel.

111. (New) The test strip of claim 104 in which said strip body includes a first substrate, a second substrate and a roof, the second substrate being positioned intermediate the first substrate and the roof and including an opening, the opening of the second substrate together with the first substrate and the roof defining the capillary channel.

112. (New) The test strip of claim 111 in which said test strip includes conductive tracks connected with said working and counter electrodes, the first substrate having first and second surfaces, the working and counter electrodes being affixed to the first surface of the first substrate, the second substrate having first and second surfaces and an opening, the second surface of the second substrate being affixed to the first surface of the first substrate, the second substrate configured to expose a portion of the conductive tracks for electrical

connection to a meter capable of measuring an electrical property, the opening being located along a perimetric edge of the second substrate and exposing said electrodes, and a roof having first and second surfaces and including a solid, transparent or translucent viewing material, the second surface of the roof being affixed to the first surface of the second substrate and positioned so that it overlays the opening of the second substrate and so that the second surface of the roof and the first surface of the first substrate form opposing walls of the capillary channel, the transparent or translucent viewing material extending from at least adjacent to the sample application port and overlying the entire width of one of the electrodes and at least about ten percent of the width of the other electrode.

113. (New) The test strip of claim 111 in which the second substrate defines opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge, to at least one of the electrodes.

114. (New) The test strip of claim 113 in which said test strip further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes.

115. (New) The test strip of claim 114 in which the opaque portions are spaced apart to reveal greater than about 75% of the width of the capillary channel.

116. (New) The test strip of claim 115 in which the opaque portions are aligned with the opposed sides of the capillary channel.

117. (New) The test strip of claim 116 in which the opaque portions are defined by the roof.

118. (New) The test strip of claim 111 in which the opening of the second substrate defines opposed sides of the capillary channel, said visualization means including opaque portions generally aligned with the opposed sides of the capillary channel extending from adjacent the sample application port to at least one of the electrodes, the opaque portions being located in the area adjacent the capillary channel, the opaque portions having a color which contrasts with the color of the sample as observed through the viewing material,

whereby a user is able to visually locate the sample within the capillary channel by observation through the viewing material and is able to determine when the sample has filled the capillary channel at least up to the at least one electrode.

119. (New) The test strip of claim 118 in which the opposed sides of the capillary channel are parallel and extend in a straight line from the sample application port, and orthogonal to the perimetric edge, to at least one of the electrodes.

120. (New) An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising:

an electrochemical test strip having a capillary channel including length and width dimensions; and

a solid, transparent or translucent visualization portion including a viewing material including a viewing area through which a portion of the blood sample within the capillary channel can be visually viewed,

wherein the viewing area of the viewing material is smaller than the area defined by the length and width of the capillary channel.

121. (New) The test strip of claim 120, wherein the viewing material operates as a confirmation window that confirms sufficient blood sample has been added to the test strip to conduct a glucose test.

122. (New) The test strip of claim 120, wherein the capillary channel is bounded on at least three sides by opaque portions that provide a color contrast between the blood sample as viewed through the viewing material and the opaque portions for ease of visually determining sample sufficiency to conduct a glucose test.

123. (New) The test strip of claim 120 in which the length of the viewing area is less than the length of the capillary channel.

124. (New) The test strip of claim 120 in which the width of the viewing area is less than the width of the capillary channel.

125. (New) The test strip of claim 124 in which the length of the viewing area is less than the length of the capillary channel.

126. (New) An electrochemical test strip for conducting testing for the concentration of an analyte in a blood sample, comprising:

a strip body including an edge extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge, the capillary channel extending from the sample application port at least to the vent;

at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the perimetric edge; and

a test reagent adjacent at least the working electrode;

said strip body defining a viewing area allowing continuous visualization of the capillary channel from a portion thereof at or generally adjacent the sample application port, up to and including said working electrode and at least a portion of said counter electrode,

the viewing area being positioned and dimensioned such that blood introduced to the capillary channel through the sample application port and filling the viewing area at least up to a portion of said counter electrode under the viewing area is required for the test strip to have a sufficient blood sample to conduct a test.

127. (New) An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising:

a strip body including an edge extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the perimetric edge, the capillary channel extending from the sample application port to at least the vent, said strip body further defining a test area along the capillary channel between the sample application port and the vent;

at least working and counter electrodes spaced from each other and positioned within the test area of the capillary channel at a location spaced from the perimetric edge;

a test reagent received within the test area of the capillary channel and adjacent at least the working electrode;

said strip body including a solid, transparent or translucent viewing material overlying at least a portion of the capillary channel, including from a portion thereof at or generally adjacent the sample application port continuously up to and including said working electrode

and at least a portion of said counter electrode, the viewing material permitting visualization of the blood sample as it moves through the capillary channel to the test area;

said strip body further including opaque portions defining a fill area viewable through the viewing material, the fill area comprising an area of the capillary channel needed to be filled to conduct an accurate test;

wherein observation through the viewing material of the blood sample within the capillary channel up to said electrodes comprises confirmation of sufficient blood sample being introduced into the capillary channel to conduct a test.

128. (New) The test strip of claim 127 in which the opaque portions are sized and dimensioned such that the blood sample is required to fill up to the electrodes the portion of the capillary channel viewable through the viewing material in order to have a sufficient amount of blood sample to conduct a test.

129. (New) The test strip of claim 127 in which the opaque portions extend continuously in alignment with the opposed sides of the capillary channel from the perimetric edge to the electrodes.

130. (New) The test strip of claim 129 in which the opaque portions are sized and dimensioned such that the blood sample is required to fill up to the electrodes the portion of the capillary channel viewable through the viewing material in order to have a sufficient amount of blood sample to conduct a test.

Support for New Claims 104-130

The new claims 104-130 are clearly supported in the original specification of this application. These claims generally relate to electrochemical test strips which provide a means for the user to visually monitor the capillary flow of blood into the test strip. Further, the user is able to visually confirm that a sufficient amount of blood has been received in the test strip in order to conduct an accurate glucose test.

General support for new claims 104-130 is found throughout the specification and the drawings. Attention is directed to the Abstract (lines 11-15), the Figures (particularly Figures 1, 3i and 5), and the disclosure found at column 1, line 61 to column 2, line 14; column 4, lines 1-48; and column 8, line 26 to column 9, line 9. In addition to these general portions of the specification, support for the claims can be found as follows:

Claims:	Support:
104. An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising:	Col. 5, lines 60-61: "In the preferred embodiment, test reagent 12 is formulated for the measurement of glucose in a human blood sample."
a strip body including an edge extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge, the capillary channel extending from the sample application port to at least the vent;	See Figures 3i and 5. Also see: Col. 4, lines 36-45: "Second surface 17 of roof 13, the edges of opening 11, and first surface 22 of insulating substrate 1 (and conductive tracks 5 and 6 affixed to first surface 22 of substrate 1) define a capillary testing chamber." Col. 8, lines 61-64: "Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable acuity to determine if the window is entirely full of sample."
at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the perimetric edge	Col. 3, lines 39-42: "In the test strip . . . . electrically conductive track 5 would be the working electrode, and electrically conductive track 6 would be a counter electrode or reference electrode."
a test reagent adjacent at least the working electrode; and	Col. 4, lines 1-4: "Second opening 11 exposes a different portion of conductive tracks 5 and 6 for application of test

	reagent 12 to those exposed surfaces of tracks 5 and 6."
visualization means associated with the capillary channel for enabling a user to visually identify when a sufficient amount of blood sample has been added to the capillary fill chamber to accurately perform a test, said visualization means including a solid, transparent or translucent viewing material extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel including at said working electrode and at least a portion of said counter electrode.	Abstract, lines 11-15: ". . . identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test." Col. 1, lines 36-36: "Further, insufficient sample may also be drawn into the capillary reaction chamber, thereby resulting in an inaccurate test result." Col. 1, line 60 to col. 2, line 4: "The window defines the minimum sample amount, or dose, required to accurately perform a test, and therefore, represents a visual failsafe which reduces the chances of erroneous test results due to underdosing of a test strip." Col. 8, line 52 to col. 9, line 9: "The dimensions of transparent or translucent window 18 should be chosen such that a substantial fraction of the width (greater than about 75%) of the underlying capillary channel is visible through window 18. The orthogonal dimension of window 18 should expose the entire width of the working electrode 5. Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. By choosing the window dimensions as just stated it is possible to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample. Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered. This coverage of the electrodes by the test sample is important to achieving an accurate test in a capillary-fill electrochemical biosensor. This visual confirmation of sufficient dosing of the test strip provides a safeguard against erroneous test results due to undetected underdosing of the test strip."
105. The test strip of claim 104 in which said visualization means includes a means for identifying when a minimum sample amount has been added to the capillary channel.	See claim 104.
106. The test strip of claim 104 in which said visualization means includes said strip body including a color in the area adjacent the capillary channel which contrasts with the color of the sample as viewed through the viewing material, whereby the user is able to visually	See claim 104. Also see: Col. 2, lines 5-14: "Preferably, the area of the roof surrounding the window is colored in a way that provides good color

locate the sample within the capillary channel by observation through the viewing material.	contrast between the sample, as observed through the window, and the roof area surrounding the window for ease of identifying sufficient dosing of the strip." Col. 8, lines 26-31: "Preferably, roof 13 is made of MELINEX 561 polyester foil, having a thickness of 5 mil. A substantially opaque ink is printed on first surface 16 in pattern 27 such that window 18 remains transparent or translucent."
107. The test strip of claim 104 in which said strip body includes opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge, to at least one of the electrodes.	See Figures 3i and 5. Also see: Col. 8, lines 26-31: "The window is positioned and dimensioned so that when the roof is affixed to surface 8, it will align with opening 11 as shown in FIG. 3h." Col. 8, line 52 to col. 9, line 9: "Finally, roof 13 is placed onto surface 8. (See FIG. 3h) It is at this stage that the transparent or translucent window 18 defined by the absence of printed ink on roof 13 must align with opening 11 as shown in FIG. 3h."
108. The test strip of claim 107 in which said strip body further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes.	Col. 8, lines 26-31: "Preferably, roof 13 is made of MELINEX 561 polyester foil, having a thickness of 5 mil. A substantially opaque ink is printed on first surface 16 in pattern 27 such that window 18 remains transparent or translucent."
109. The test strip of claim 108 in which the opaque portions are spaced apart to reveal greater than about 75% of the width of the capillary channel.	Col. 8, line 52 to col. 9, line 9: "The dimensions of transparent or translucent window 18 should be chosen such that a substantial fraction of the width (greater than about 75%) of the underlying capillary channel is visible through window 18.
110. The test strip of claim 109 in which the opaque portions are aligned with the opposed sides of the capillary channel..	See claims 107-109.
111. The test strip of claim 104 in which said strip body includes a first substrate, a second substrate and a roof, the second substrate positioned intermediate the first substrate and the roof and including an opening, the opening of the second substrate together with the first substrate and the roof defining the capillary channel.	See Figures 3i and 5. Also see: Col. 4, lines 36-45: "Second surface 17 of roof 13, the edges of opening 11, and first surface 22 of insulating substrate 1 (and conductive tracks 5 and 6 affixed to first surface 22 of substrate 1) define a capillary testing chamber." Col. 8, lines 61-64: "Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable acuity to determine if the window is entirely full of sample."
112. The test strip of claim 111 in which said test strip includes conductive tracks connected with said working	See claim 104 and the Figures.

and counter electrodes, the first substrate having first and second surfaces, the working and counter electrodes being affixed to the first surface of the first substrate, the second substrate having first and second surfaces and an opening, the second surface of the second substrate being affixed to the first surface of the first substrate, the second substrate configured to expose a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the opening being located along a perimetric edge of the second substrate and exposing said electrodes, and a roof having first and second surfaces and including a solid, transparent or translucent viewing material, the second surface of the roof being affixed to the first surface of the second substrate and positioned so that it overlays the opening of the second substrate and so that the second surface of the roof and the first surface of the first substrate form opposing walls of the capillary channel, the transparent or translucent viewing material extending from at least adjacent to the sample application port and overlying the entire width of one of the electrodes and at least about ten percent of the width of the other electrode.	
113. The test strip of claim 111 in which the second substrate defines opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge, to at least one of the electrodes.	See claims 107-109.
114. The test strip of claim 113 in which said test strip further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes.	See claims 107-109.
115. The test strip of claim 114 in which the opaque portions are spaced apart to reveal greater than about 75% of the width of the capillary channel.	See claim 109.
116. The test strip of claim 115 in which the opaque portions are aligned with the opposed sides of the capillary channel.	See claims 106-109.
117. The test strip of claim 116 in which the opaque portions are defined by the roof.	Col. 8, lines 26-31: "Preferably, roof 13 is made of MELINEX 561 polyester foil, having a thickness of 5 mil. A substantially opaque ink is printed on first surface 16 in pattern 27 such that window 18 remains transparent or translucent."
118. The test strip of claim 111 in which the opening of the second substrate defines opposed sides of the capillary channel, said visualization means including opaque portions generally aligned with the opposed sides of the capillary channel extending from adjacent the sample application port to at least one of the electrodes, the opaque portions being located in the area adjacent the capillary channel, the opaque portions having a color which contrasts with the color of the sample as observed through the viewing material,	See claims 107-109.
whereby a user is able to visually locate the sample within	See claim 104.

the capillary channel by observation through the viewing material and is able to determine when the sample has filled the capillary channel at least up to the at least one electrode.	
119. The test strip of claim 118 in which the opposed sides of the capillary channel are parallel and extend in a straight line from the sample application port, and orthogonal to the perimetric edge, to at least one of the electrodes.	See claims 107-109.
120. An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising:	See claim 104.
an electrochemical test strip having a capillary channel including length and width dimensions; and	See claim 104 and Figures 3i and 5.
a solid, transparent or translucent visualization portion including a viewing material including a viewing area through which a portion of the blood sample within the capillary channel can be visually viewed,	See claim 104.
wherein the viewing area of the viewing material is smaller than the area defined by the length and width of the capillary channel.	See Figures 3i and 5. Also see: Col. 8, line 52 to col. 9, line 9: "The dimensions of transparent or translucent window 18 should be chosen such that a substantial fraction of the width (greater than about 75%) of the underlying capillary channel is visible through window 18. The orthogonal dimension of window 18 should expose the entire width of the working electrode 5. Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. By choosing the window dimensions as just stated it is possible to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample. Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered. This coverage of the electrodes by the test sample is important to achieving an accurate test in a capillary-fill electrochemical biosensor. This visual confirmation of sufficient dosing of the test strip provides a safeguard against erroneous test results due to undetected underdosing of the test strip."
121. The test strip of claim 120, wherein the viewing material operates as a confirmation window that confirms sufficient blood sample has been added to the test strip to conduct a glucose test.	See claim 104.
122. The test strip of claim 120, wherein the capillary channel is bounded on at least three sides by opaque portions that provide a color contrast between the blood sample as viewed through the viewing material and the opaque portions for ease of visually determining sample	See claims 104 and 106, and Figures 3i and 5.

sufficiency to conduct a glucose test.	
123. The test strip of claim 120 in which the length of the viewing area is less than the length of the capillary channel.	See Figures 3i and 5. Also see: Col. 2, lines 5-14: "The length and width of the window are shorter than the length and width of the capillary test chamber. The window is dimensioned and positioned so that it overlays the entire width of the working electrode and at least about 10% of the width of the counter or reference electrode of the biosensor test strip."
124. The test strip of claim 120 in which the width of the viewing area is less than the width of the capillary channel.	See claim 123.
125. The test strip of claim 124 in which the length of the viewing area is less than the length of the capillary channel.	See claim 123.
126. An electrochemical test strip for conducting testing for the concentration of an analyte in a blood sample, comprising: a strip body including an edge extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge, the capillary channel extending from the sample application port at least to the vent; at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the perimetric edge; and a test reagent adjacent at least the working electrode; said strip body defining a viewing area allowing continuous visualization of the capillary channel from a portion thereof at or generally adjacent the sample application port, up to and including said working electrode and at least a portion of said counter electrode, the viewing area being positioned and dimensioned such that blood introduced to the capillary channel through the sample application port and filling the viewing area at least up to a portion of said counter electrode under the viewing area is required for the test strip to have a sufficient blood sample to conduct a test.	See claim 104.
127. An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising: a strip body including an edge extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the perimetric edge, the capillary channel extending from the sample application port to at least the vent, said strip body further defining a test area along the capillary channel between the	See claim 104 and Figures 3i and 5.

sample application port and the vent; at least working and counter electrodes spaced from each other and positioned within the test area of the capillary channel at a location spaced from the perimetric edge; a test reagent received within the test area of the capillary channel and adjacent at least the working electrode; said strip body including a solid, transparent or translucent viewing material overlying at least a portion of the capillary channel, including from a portion thereof at or generally adjacent the sample application port continuously up to and including said working electrode and at least a portion of said counter electrode, the viewing material permitting visualization of the blood sample as it moves through the capillary channel to the test area;	
said strip body further including opaque portions defining a fill area viewable through the viewing material, the fill area comprising an area of the capillary channel needed to be filled to conduct an accurate test; wherein observation through the viewing material of the blood sample within the capillary channel up to said electrodes comprises confirmation of sufficient blood sample being introduced into the capillary channel to conduct a test.	See claims 107-109 and the Figures.
128. The test strip of claim 127 in which the opaque portions are sized and dimensioned such that the blood sample is required to fill up to the electrodes the portion of the capillary channel viewable through the viewing material in order to have a sufficient amount of blood sample to conduct a test.	See claim 104 and the Figures.
129. The test strip of claim 127 in which the opaque portions extend continuously in alignment with the opposed sides of the capillary channel from the perimetric edge to the electrodes.	See claim 104 and the Figures.
130. The test strip of claim 129 in which the opaque portions are sized and dimensioned such that the blood sample is required to fill up to the electrodes the portion of the capillary channel viewable through the viewing material in order to have a sufficient amount of blood sample to conduct a test.	See claim 104.